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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/974,584	11/19/1997	THOMAS R. CECH	015389-00295	8401

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/974,584	CECH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119 and 127-131* is/are pending in the application.

4a) Of the above claim(s) *127,128,130 and 131* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119 and 129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/06;10/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2006 has been entered.

Applicant's arguments and amendments set forth in the response of March 14, 2006 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. In particular, the obviousness-type double patenting rejection of claim 119 over U.S. Patent 6,767,719 is withdrawn in view of the amendment to the claim to recite that the claimed polynucleotide does not encode a protein having 500 contiguous amino acids encoded by SEQ ID NO: 124. This recitation in the claims excludes the polynucleotides claimed in '719. Further, the obviousness-type double patenting rejection does not apply to newly added claim 129 because this claim requires a polynucleotide encoding for a protein having at least 80% identity with SEQ ID NO: 118 when the entire sequence of said protein is optimally aligned with SEQ ID NO: 118.

Additionally, the rejection of claim 119 under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,093,809) is withdrawn in view of the 132 Declaration of Calvin Harley filed March 14, 2006.

Election/Restrictions

2. Newly submitted claims 128 and 130 are directed to an invention, i.e. proteins, that is independent or distinct from the elected invention of polynucleotides. The subject matter of claims 128 and 130 was restricted in the Office action of September 26, 2000. In the response of January 9, 2000, Applicants elected the invention of polynucleotides encoding telomerase reverse transcriptase. The election was treated as an election without traverse because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement. Accordingly, claims 128 and 130 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Further, it is noted that the response requests rejoinder of withdrawn claims 127 and 131 upon the determination that the product claims are allowable. states that "upon establishing that claim 119 is free of prior art, then claim 127 will also be free of prior art. For this reason, it is requested that claim 127 be rejoined with the group under examination, in accordance with MPEP § 821.04." However, claims 19 and 129, drawn to the elected product, have not been found to be allowable. Accordingly, claims 127 and 131 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 119 and 129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new grounds of rejection.**

Claim 119 is indefinite over the recitation of "optimally aligned with SEQ ID NO: 118, with each of the following structures in the order shown" because the claim does not clearly set forth what the term "with" is intended to refer back to. Similarly, claim 129 is indefinite over the recitation of "optimally aligned with SEQ ID NO: 118, each of the following structures" because it is not clear as to what the phrase "each of the following structures" is intended to refer back to. These rejections may be overcome by amendment of the claims to recite, for example, "optimally aligned with SEQ ID NO: 118, wherein said protein contains each of the following structures in the order shown..."

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 119 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new grounds of rejection.**

The specification as originally filed does not appear to provide support for the recitation in amended claim 119 of "with the proviso that said protein is not a mouse

telomerase reverse transcriptase protein, characterized as having at least 500 consecutive amino acids encoded by SEQ ID NO: 124."

In the reply filed March 14, 2006, Applicants state that the proviso language has been added to the claims in accordance with the MPEP 2173.05(i) which allows for the exclusion of any elements positively recited in the specification. It is asserted that the specification teaches SEQ ID NO: 124, and generally refers to TRT sequences of 500 amino acids in length. Thereby, Applicants conclude that the specification provides support for the exclusion of polynucleotides encoding a protein that is a mouse reverse transcriptase having at least 500 consecutive amino acids encoded by SEQ ID NO: 124.

Applicants arguments have been fully considered but are not persuasive. It is agreed that it is permissible to exclude from the claims specific embodiments that are positively recited in the specification. For instance, since the specification discloses the sequence of SEQ ID NO: 124 and proteins encoded thereby, this disclosure provides basis for the concept of polynucleotides encoding a protein having 60% identity with SEQ ID NO: 118 and having the structures set forth in claim 119, wherein the polynucleotide does not encode for the amino acid sequence encoded by SEQ ID NO: 124. However, in the present situation, the claim does not exclude a specific embodiment that was positively recited in the originally filed specification. Rather, the present claim seeks to exclude any polynucleotide encoding any "mouse telomerase reverse transcriptase protein" wherein the mouse protein has any 500 consecutive amino acids encoded by SEQ ID NO: 124.

Regarding the language "mouse telomerase reverse transcriptase protein," the specification does not disclose what is intended to be encompassed by a mouse reverse transcriptase protein and does not teach how one would distinguish a mouse reverse transcriptase protein over any other reverse transcriptase protein. Accordingly, the recitation of "mouse" does not impart any particular functional or structural limitations onto the protein. For these reasons, the specification as originally filed does not provide adequate basis to exclude the subgenus of polynucleotides encoding for any undefined mouse TRT. Further, as discussed in the response of March 14, 2006, SEQ ID NO: 124 does not encode for the full length mouse protein. Rather, this sequence "represents a preliminary sequence for a portion of the native mouse TRT cDNA, encoding the N-terminal 691 amino acids of the mouse TRT protein sequence." Thereby, the disclosure of a polynucleotide encoding a portion of a mouse TRT does not provide basis for the concept of excluding any polynucleotide encoding for any full length mouse TRT. Further, the fact that the specification discusses TRT sequences of 500 amino acids does not provide basis for the concept of specifically excluding a subgenus of polynucleotides which encode for a mouse TRT and which contain at least 500 amino acids encoded by SEQ ID NO: 124.

It is also noted that the response asserts that "At least part of the residues 192-450 are needed for activity of human TRT (U.S. patent 6,337,200, Table 1) and mutation of the "T" motif can also remove activity (U.S. Patent 6,166,178, Example 16). Hence, any portion of the mouse TRT sequence lacking residues 190-460, or lacking residues 530-580 (covering the "T" motif) would presumably lack telomerase activity.

This means that no fragment of native mouse TRT lacking 500 or more consecutive amino acids in SEQ ID NO :124 would be expected to have telomerase activity." These statements exemplify the subgenus of polynucleotides that the newly added claim language seeks to exclude. However, the specification as originally filed does not appear to have contemplated this particular subgenus of polynucleotides (i.e., any TRT sequences lacking residues 190-460 or residues 530-580) and thereby does not provide basis to specifically exclude this subgenus of polynucleotides.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '836 are drawn to a polynucleotide encoding a specific

telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '836. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '836 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 224 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 224 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '836 are encompassed by the presently claimed polynucleotides encoding any TRT.

RESPONSE TO ARGUMENTS:

In the response, Applicants do not specifically address this rejection. Accordingly, the rejection is maintained and made final for the reasons stated above.

The following are new grounds of rejection:

6. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 29, 32-33 and 99-121 of copending Application No. 09/721,477. Although the present claims and the claims of '477 are not identical, they are not patentably distinct from each other because the present claims and the claims of '477 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-50 of copending Application No. 10/877,124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '124 are both inclusive of nucleic acids encoding a human TRT having 10 or more amino acids of SEQ ID NO: 2. The present claims are also encompassed by the claims of '124 which are inclusive of nucleic acids encoding SEQ ID NO: 2 and having a mutation that reduces telomerase activity since the present claims encompass variants having 60% identity with a sequence encoding hTRT.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 29, 32-33 and 1-33 and 36-40 of copending Application No. 10/044,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '539 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 75-78, 102, 105-108 of copending Application No. 09/721,506. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the present claims and the claims of '506 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-26 and 28 of copending Application No. 11/207,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '078 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 119 and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 19-33, 39-43, 47-57 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '692 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,927,285. Although the conflicting claims and the claims of '285 are not identical, they are not patentably distinct from each other because the present claims and the claims of '285 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

13. Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,921,664. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '644 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

14. Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,337,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '200 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

15. Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,475,789. Although the conflicting claims and the claims of '789 are not identical, they are not patentably distinct from each other because the present claims

and the claims of '789 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

16. Claims 119 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,444,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '650 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 119 and 129 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding human telomerase and having the sequence of present SEQ ID NO: 118. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

RESPONSE TO ARGUMENTS:

In the response, Applicants did not specifically address this rejection. Again, it is noted that the inventorship of the '867 patent (Thomas R. Cech and Toru Nakamura) is

distinct from the inventorship of the present application and thereby the '867 constitutes prior art under 102(e).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
May 17, 2006

CARLA J. MYERS
PRIMARY EXAMINER